510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
k043197

B. Purpose for Submission:
Clearance of new claim for alternate site testing on the palm when the patient is in the steady state

C. Measurand:
Capillary blood glucose

D. Type of Test:
Quantitative enzymatic (glucose oxidase) electrochemical assay

E. Applicant:
Lifescan, Inc.

F. Proprietary and Established Names:
OneTouch Ultra, Induo, and Ultrasmart Blood Glucose Monitoring Systems

G. Regulatory Information:

1. Regulation section:
   21 CFR §862.1345, Glucose test system

2. Classification:
   Class II

3. Product code:
   NBW, System, test, blood glucose, over the counter
   CGA, glucose oxidase, glucose

4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

The OneTouch Ultra, Induo, and Ultrasmart Blood Glucose Monitoring Systems are intended to be used for quantitative measurement of glucose in fresh capillary whole blood. The OneTouch Ultra, Induo, and Ultrasmart Blood Glucose Monitoring Systems are intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

2. Indication(s) for use:

The OneTouch Ultra, Induo, and Ultrasmart Blood Glucose Monitoring Systems are intended to be used for quantitative measurement of glucose in fresh capillary whole blood. The OneTouch Ultra, Induo, and Ultrasmart Blood Glucose Monitoring Systems are intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

The OneTouch Ultra, Induo, and Ultrasmart Blood Glucose Monitoring Systems are specifically indicated for use on the finger, arm or palm.

3. Special conditions for use statement(s):

For over-the-counter or professional use

Patients should not test on the palm when they think their blood glucose is rapidly falling, such as within two hours of exercise or a rapid-acting insulin injection or insulin pump bolus. Testing with a fingertip sample may identify a hypoglycemic (low blood sugar) level sooner than a test with a forearm or palm sample.

Patients should not test on the palm when it has been less than two hours after a meal, a rapid-acting insulin injection or insulin pump bolus, physical exercise, or they think their glucose level is changing rapidly.

Patients should not test on the palm when they are concerned about the possibility of hypoglycemia.

The OneTouch® InDuo® Blood Glucose Meter also functions as the cap for the InDuo® Insulin Doser. The two devices fit together to form a single unit for user convenience.

The OneTouch UltraSmart® Blood Glucose Monitoring System provides the user with electronic logbook functions that store data such as insulin and oral medication doses, food intake, amount of exercise, and health information such as illness. The meter includes a data port that enables the user to download electronic data to a personal computer.

4. Special instrument requirements:

OneTouch Ultra, Induo, or Ultrasmart Blood Glucose Monitoring Systems

I. Device Description:

The OneTouch Ultra, Induo, and Ultrasmart Blood Glucose Monitoring Systems are in vitro diagnostic products consisting of a test strip impregnated with reagents and a reflectance photometer for the determination of glucose in whole blood. A quality control solution, ancillary devices to aid obtaining a capillary blood sample (lancets and lancing device), and data management computer software are also available.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Lifescan OneTouch Ultra Blood Glucose Monitoring System

Lifescan OneTouch UltraSmart Blood Glucose Monitoring System
Lifescan OneTouch Ultra and OneTouch InDuo Blood Glucose Monitoring Systems
Lifescan InDuo Blood Meter
Freestyle Blood Glucose Monitoring System
BD Logic and Paradigm Link Blood Glucose Monitoring Systems

2. Predicate 510(k) number(s):
k002134, k021819, k024194, k011616, k031260,k041478

3. Comparison with predicate:
The device is the same device as the predicate OneTouch Ultra Blood Glucose Monitoring System except that the Indications for Use have been expanded to include palm alternate site testing when the patient is in the steady state.

K. Standard/Guidance Document Referenced (if applicable):

FDA Guidance Document: Review Criteria for Assessment of Portable Blood Glucose In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology
ISO 15197: Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

L. Test Principle:

The test system works by using glucose oxidase biosensor technology. When blood is applied to a test strip inserted into the meter port, the reagents on the strip react with the glucose in the blood to generate small electrical currents. The meter automatically starts and controls the test timing. It measures the electrical currents that are produced to calculate the glucose result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable. Analytical Performance Characteristics cleared in previous 510(k) submissions (e.g. k002134, k021819, and k024194)

b. Linearity/assay reportable range:

Not applicable. Analytical Performance Characteristics cleared in previous 510(k) submissions (e.g. k002134, k021819, and k024194)

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Not applicable. Analytical Performance Characteristics cleared in previous 510(k) submissions (e.g. k002134, k021819, and k024194)

d. Detection limit:

Not applicable. Analytical Performance Characteristics cleared in previous 510(k) submissions (e.g. k002134, k021819, and k024194)

e. Analytical specificity:

Not applicable. Analytical Performance Characteristics cleared in previous 510(k) submissions (e.g. k002134, k021819, and k024194)

f. Assay cut-off:
Not applicable

2. Comparison studies:
   a. Method comparison with predicate device:

See Matrix Comparison below for a comparison of fingertip and palm testing.

b. Matrix comparison:

To evaluate the lay-user performance of alternate site testing in the steady state using the palm, test subjects (diabetic lay users) were provided with the device and asked to do a minimum of two blood glucose tests daily using the palm (one from the thenar and one from the hypothenar). Subjects were instructed not to make any treatment decisions based on the test results.

For the second phase of the study, test subjects reported to the study site in a steady state condition (defined as at least 2 ours after a meal, insulin dose, or physical exercise). The subjects tested themselves using blood from the palm under the observation of a healthcare professional. The healthcare professional then performed tests from the palm and two fingertips. The subjects then consumed a meal and took their usual insulin dose or hypoglycemic medication. The subjects were tested again by the healthcare professionals at predetermined time points over 4 hours for adults or 2 hours for pediatric subjects. At one of time points (chosen randomly), the subject performed their own tests. Hypoglycemic is defined as glucose concentration ≤ 60 mg/dL, Euglycemic is defined as glucose concentration > 60 and ≤ 140 mg/dL, and Hyperglycemic is defined as glucose concentration > 140 mg/dL. Results, summarized below, support the performance of alternate site testing on the palm when the patient is in the steady state.

Reference Blood Glucose	**Steady State Data - Difference, Palm – Finger (in % if reference concentration > 75 mg/dL, else in mg /dL)**										**Total**
	> 20		**± 20**		**± 15**		**± 10**		**± 5**		
	n	***% or mg/dL***	***n***	***% or mg/dL***	***n***	***% or mg/dL***	***n***	***% or mg/dL***	***n***	***% or mg/dL***	***n***
≤75 mg/dL	1	3.2	30	96.8	28	90.3	25	80.6	14	45.2	31
>75 mg/dL	29	3.9	718	96.1	669	89.6	550	73.6	333	44.6	747
All	30	3.9	748	96.1	697	89.6	575	73.9	347	44.6	778

Steady state data	palm to finger		finger to finger	
	# points	% pass**	# points	% pass**
Subject only	106	93.3 %	106	97.1 %
HCP*	672	96.2 %	675	97.6 %
HCP + Subj.	778	95.8 %	781	97.5 %

* HCP = healthcare professional

** acceptable results are defined as being within 15 mg/dL in samples ≤ 75 mg/dL glucose or within 20% in samples > 75 mg/dL glucose

Deming regression analysis on the data from the matched palm and fingertip samples was performed. Regression statistics are summarized below:

	Intercept	Lower 95% CI	Upper 95% CI	Slope	Lower 95% CI	Upper 95% CI
Steady State	1.24	0.31	2.45	0.9704	0.9643	0.9765

Results, analyzed to compare two palm sites (thenar and hypothenar), are summarized below:

	Steady State Data			
	palm to finger		finger to finger	
Data Set	# points	% pass*	# points	% pass*
Hypothenar	403	95.0 %	407	97.2 %
Thenar	375	96.8 %	374	97.8 %

* passing results are defined as being within 15 mg/dL in samples ≤ 75 mg/dL glucose or within 20% in samples > 75 mg/dL glucose

Results comparing data from adult subjects to pediatric subjects is summarized below. The device seems to perform equivalently in pediatric subjects and adults.

	Steady State Data			
	palm to finger		finger to finger	
Data Set	# points	% pass*	# points	% pass*
Pediatric	99	98.99%	99	96.97 %
Adult	679	95.43 %	682	97.65 %

* passing results are defined as being within 15 mg/dL in samples ≤ 75 mg/dL glucose or within 20% in samples > 75 mg/dL glucose

An analysis of the Mean Absolute Percentage Error (MAPE) was performed to examine the differences between Palm and Reference Finger compared to differences between Comparator Finger and Reference Finger. Data are summarized below:

Data Subset		N	MAPE	SD	Stand Error	Lower 95% CI	Upper 95% CI
Total	Palm	778	7.49	6.84	0.25	7.01	7.97
	Finger	781	6.34	6.07	0.22	5.91	6.76
HCP Tests	Palm	672	7.42	6.76	0.26	6.91	7.93
	Finger	675	6.30	5.43	0.21	5.89	6.71
Subj Tests	Palm	106	7.92	7.31	0.71	6.51	9.32
	Finger	106	6.58	9.21	0.89	4.80	8.35
Pediatrics	Palm	99	6.63	4.75	0.48	5.68	7.58
	Finger	99	6.75	5.00	0.50	5.75	7.74
Adults	Palm	679	7.61	7.08	0.27	7.08	8.15
	Finger	682	6.28	6.21	0.24	5.81	6.74
Hypothenar	Palm	403	7.73	7.73	6.87	0.34	7.05
	Finger	407	5.86	5.12	0.25	5.36	6.36
Thenar	Palm	375	7.23	6.81	0.35	6.54	7.92
	Finger	374	6.86	6.93	0.36	6.15	7.56

3. Clinical studies:
   a. *Clinical Sensitivity:*
   See Matrix Comparison above for clinical information.

   b. *Clinical specificity:*
   See Matrix Comparison above for clinical information.

   c. Other clinical supportive data (when a. and b. are not applicable):

During the study, palm testing was first conducted at home to provide subjects an opportunity to read the investigational labeling and experience palm testing prior to reporting to the clinic for observation and equivalency testing. All data was self-reported. This phase of the study involved initial exposure to palm lancing. The palm testing evaluation (Study Visit) incorporated a human factors evaluation as well as provided a controlled formal evaluation of palm lancing. Subjects performed a test on the palm under the observation of a Health Care Professional (HCP) using only the labeling as a guide. This testing was done at the beginning of the study visit, prior to the palm equivalency testing performed by the HCPs. Targeted aspects of subject performance were recorded by the HCP. A total of 181 subjects performed blood glucose self-tests on the palm using the device and investigational labeling. HCPs

observed and evaluated the test without providing assistance or guidance to the subjects. Subjects were allowed up to two tests to obtain a numeric result. If the subjects did not obtain a numeric result on the first test, they were instructed to re-read the investigational AST Booklet and repeat the test on the palm. The subject could choose the area of the palm to test. Of the 181 subjects participating in the study, 152 (84.0%) of subjects were able to obtain a numeric result after the 1st attempt. A total of 29 (16%) subjects, who did not obtain a numeric result on the 1st attempt, re-read the labeling and repeating the test. After the 2nd attempt all but 3 subjects were able to obtain a numeric result. Analysis of the data suggested that problems were a result of patients using the wrong cap on the lancet despite labeling. To address this, additional emphasis and clarity were added to the labeling regarding 1) obtaining a sufficient blood sample from the palm and 2) which sampler cap to use for alternative site testing.

4. Clinical cut-off**:**
   Not applicable

5. Expected values/Reference range:
   The expected blood glucose levels for people without diabetes are as follows:

Time	**Range (mg/dL)**
Before breakfast	70 – 105
Before lunch or dinner	70 – 110
1 hour after meals	< 160
2 hours after meals	< 120
Between 2 and 4 AM	> 70

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.